

[2010] [SP0136] PREPARING NEW REGULATORY GUIDELINES: THE ROLE OF THE GROUP FOR THE RESPECT OF ETHICS AND EXCELLENCE IN SCIENCE (GREES)

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Regulatory guidelines for the registration of new chemical entities represent the cornerstone of the clinical development for new medications. They usually extensively describe the various steps leading a pharmaceutical company, usually called the Applicant, to seek for marketing authorization. These guidelines start from Phase I studies towards the final steps, including Phase III pivotal trials. At this stage, regulatory agencies, in Europe the Committee for Human Medicinal Products (CHMP), at the European Medicine Evaluation Agency (EMA), will assess the risk/benefit ratio of a new chemical entity, taking into account its efficacy and safety in a particular indication. In order to make sure that these regulatory guidelines do meet the highest scientific level, it is of prime importance to facilitate interactions between members of the regulatory authorities, academics scientists and representatives of the pharmaceutical industry. The Group for the Respect of Ethics and Excellence in Science (GREES) is a not-for-profit organization, registered in Belgium, in 1985. It works by invitation only and is currently listed as an "interested body" with EMA. GREES has, for objective, to organize meetings with representatives of regulatory authorities, academic scientists and experts from the pharmaceutical industry. It works on the basis of "ad hoc" sections, activated at the request of regulatory authorities or pharmaceutical industry when scientific issues are raised, during the preparation of guidelines for the registration of new chemical entities in a specific medical area. The objective of the GREES is to prepare working documents, that will be submitted to regulatory authorities and, if deemed necessary, will serve as preliminary working documents for National or European regulatory authorities. GREES participants work on a pro-bono basis and no funding is provided to the GREES by the pharmaceutical industry. So all GREES members are fully independent and GREES meetings do not generate competing interests. The outcomes of the GREES meetings are published, within 12 months of the first meeting of a specific working group, in a first-line peer-reviewed Journal in the field. Several ad hoc sections have been constituted, over the years, dealing primarily with musculoskeletal disorders (e.g. Postmenopausal Osteoporosis, Osteoporosis in men, Glucocorticoid-induced Osteoporosis, Osteoarthritis, Rheumatoid Arthritis, Bone Fracture Healing, ...) but also with other areas of medicine (e.g. Asthma and Chronic Obstructive Pulmonary Disorders, Hormone Replacement Therapy, Pharmacogenetics, Ethics, Adherence, Health Economics, Climacteric Symptoms, ...). Whereas the GREES still constitutes an informal group of interaction between scientists coming from various areas, it is now well accepted, within the scientific community as one of the most prominent scientific groups, working in perspective of improving patient' well-being.

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Do we need "new points to consider for RA clinical trials?"

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